REMARKS

This Amendment is responsive to the Office Action dated July 18, 2006. Applicant has added claims 15-18. Claims 1-18 are pending.

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 1-7, 9, 10, 13 and 14 under 35 U.S.C. § 102(b) as being anticipated by Kirkpatrick et al. (U.S. Patent No. 6,408,743). Applicant respectfully traverses the rejection. Kirkpatrick et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Kirkpatrick fails to disclose or suggest an implantable medical device comprising an overmold that at least partially encapsulates each of at least two housings, as required by independent claim 1. In a previous Office Action mailed on January 3, 2006, the Examiner argued that the housing 226 depicted in FIG. 2 of Kirkpatrick et al. containing the CPU 428 and Power Supply 432 depicted in FIG. 4 of Kirkpatrick et al. meets each and every element of Applicant's claim 1. Applicant maintains the position that the Examiner's characterization of housing 226 as an overmold within the meaning of Applicant's claim 1 is improper.

Even assuming the housing 226 of the Kirkpatrick et al. device 110 is an "overmold," the arrangement of the components of the Kirkpatrick device identified by the Examiner does not anticipate the above-identified requirements of claim 1. In particular, Kirkpatrick et al. fails to teach or suggest that the housing 226 at least partially encapsulates the respective housings of at least two interconnected modules.

First, Kirkpatrick et al. fails to teach or suggest an implantable medical device comprising at least two interconnected modules each comprising a respective one of at least two housings. The Examiner interpreted the battery and microcontroller as being modules. In particular, the Office Action stated that "the Kirkpatrick et al. patent also teaches the use of a battery . . . as well as a microcontroller . . . each inherently possessing respective housings to contain their respective components." (Office Action at page 2.) Applicant respectfully disagrees with the Examiner's interpretation of Kirkpatrick et al., because the Examiner relied on an improper finding of an inherent disclosure in Kirkpatrick et al. The fact that a certain characteristic may be

present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112. Nothing in Kirkpatrick et al. reasonably supports the assertion that the battery and microcontroller of the Kirkpatrick et al. device are necessarily enclosed in a housing other than the housing 226 so as to be considered modules each comprising a respective one of at least two housings.

In fact, the Kirkpatrick et al. disclosure suggests that the housing 226, which the Examiner refers to as an overmold, is the only housing that encloses the battery and microcontroller. In particular, Kirkpatrick et al. explicitly states that, "the housing 226 encloses a battery and any electronic circuitry necessary or desirable to provide the functionality described herein . . ." (Col. 9, ll. 12-15.) Nothing in Kirkpatrick et al. suggests that the "electronic circuitry" is a module comprising a housing other than the housing 226 for the device 110. Based on the failure of Kirkpatrick et al. to teach or suggest a housing other than housing 226 for the device 110 itself, the characteristic the Examiner contends is inherent (i.e., the implantable medical device comprising an overmold that at least partially encapsulates each of at least two housings) does not necessarily flow from the teachings of Kirkpatrick et al.

Similar to independent claim 1, independent claim 9 requires an overmold and a plurality of housings. For the reasons stated above with respect to claim 1, Kirkpatrick et al. fails to disclose or suggest this element of claim 9. Accordingly, Kirkpatrick et al. does not teach each and every element of Applicant's independent claims 1 and 9, and the rejection to claims 1 and 9 under 35 U.S.C. § 102(b) should be withdrawn.

Independent claim 9, as well as claims 3 and 4, which depend from independent claim 1, also require an overmold comprising a first material and a second material. Kirkpatrick et al. fails to disclose or suggest this requirement of claim 9. In rejecting claim 9, the Examiner argued "the overmold of the Kirkpatrick et al. patent comprising a first material is configured to hold . . . a lead connection module . . . being made of a second biocompatible plastic." The Examiner relies on column 8, lines 47-54 as teaching a lead connection module being made of a second

biocompatible material. At column 8, lines 47-54, Kirkpatrick et al. merely states that the "lead connector 220 acts to physically sure the lead 22 to the device 110 . . . the lead connector 220 accomplishes this in a substantially fluid-tight environment with biocompatible materials." To the extent Kirkpatrick et al. discusses the materials its housing 226 (which the Examiner asserts is the overmold) is formed of, Kirkpatrick et al. only mentions that the housing 226 may be formed of a biocompatible material, such as titanium. (Col. 9, lines 8-12.) Even when these two passages of Kirkpatrick et al. are taken together, Kirkpatrick et al. does not teach an overmold comprising a first material and a second material. Nothing in Kirkpatrick et al. teaches or suggests that the "biocompatible materials" referred to with respect to the lead connector 220 and housing 226 are a first and second material, respectively. Thus, Kirkpatrick et al. does not anticipate Applicant's claims 3, 4, and 9.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[1] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper. [2]

As established above, Kirkpatrick et al. fails to disclose each and every limitation set forth in independent claims 1 and 9. Claims 2-8 depend from claim 1 and claims 10-14 depend from claim 9. As established above, independent claims 1 and 9 are patentable over Kirkpatrick et al., and as a result, all claims depending therefrom are also patentable over the cited references. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-14 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 8, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Kirkpatrick et al.. Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and

[1] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[2] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. In view of the fundamental deficiencies in the Kirkpatrick et al. reference identified above, it is not necessary to discuss in detail the additional patentable differences presented by the various dependent claims. However, Applicant addresses some of the rejections below for purposes of illustration.

With respect to the rejection of claims 11 and 12, which specify that the overmold comprises a first material and a second material, where the second material is an elastomeric material, the Office Action asserted that it would have been obvious to modify the Kirkpatrick et al. device to include an elastomeric material. (Office Action at page 5.) Applicant respectfully disagrees.

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.[3] In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.[4] A prima facie case of obviousness is established only when this burden is met. A finding of motivation must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.[5] Accordingly, the Examiner cannot rely on unsupported, conclusory statements, such as "it would have been obvious . . . to modify the implantable device as taught by Kirkpatrick et al. [to comprise] an elastomeric material" (Office Action at page 5) to close holes in the evidentiary record.[6]

The Examiner cited no prior art teaching as the source for the motivation, and the conclusion of obviousness advanced by the Examiner relies on a motivation plucked directly from Applicants' own disclosure, rather than the prior art. As Applicant's disclosure recognizes, an implantable medical device having a flexible structure (i.e., being formed at least in part of an elastomeric material) permits the device to conform to fit each individual patient. In particular, the novel configuration of the implantable medical device combined with the elastomeric material provides the device with such advantages. The mere fact that elastomeric materials existed at the time of the Kirkpatrick et al. invention is insufficient to render claims 11 and 12

[3] *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).
[4] *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).
[5] *In re Lee*, 61 USPQ2d 1430, 1434 (CAFC 2002).
[6] *Id.*

obvious in view of Kirkpatrick et al. The Examiner failed to explain why one of ordinary skill in the art would have considered it desirable to modify the Kirkpatrick et al. housing 226 to comprise an elastomeric material, especially considering the fact that Kirkpatrick et al. only provides titanium as an example of a suitable biocompatible material. (Col. 9, lines 8-12.) Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to incorporate the features of Applicant's dependent claims 11 and 12, the claims should be allowed.

In summary, the Examiner's conclusion of obviousness, and particularly, the asserted motivation to modify Kirkpatrick et al. device to include a housing comprising an elastomeric material is unsupported by any substantial evidence in the record. For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 11 and 12 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claims:

Applicant has added claims 15-18 to the pending application. The applied reference fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, Kirkpatrick et al. fails to disclose or suggest housings that are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold, as required by new claim 15. As another example, Kirkpatrick et al. fails to disclose or suggest an overmold that partially encapsulates at least two housings and defines a frame configured to fix a position of at least two interconnected modules relative to each other, as recited by new independent claim 16. No new matter has been added by the new claims.

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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